European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

OPINION FOLLOWING AN ARTICLE 33 (4) REFERRAL

FOR BOVILIS BVD/BOVILIS BVD-MD

BACKGROUND INFORMATION

Bovilis BVD/Bovilis BVD-MD is an inactivated virus vaccine containing the inactivated antigen of cytopathic BVD virus strain C-86. The product is indicated for the active immunisation of cows and heifers from eight months of age onwards to protect the foetus against transplacental infection with BVDV. Bovilis BVD was first authorised in Germany as Bovilis BVD-MD. The initial mutual recognition procedure was finalised on 24 June 1999 and eleven other Member States authorised the product at this time. The first renewal procedure for the vaccine was finalised in June 2004.

In March 2006 an application for a marketing authorisation for this vaccine was submitted, following a repeat use mutual recognition procedure, with Germany acting as Reference Member State.

Denmark could not agree with the granting of the marketing authorisation and the matter was referred to the Co-ordination Group for Mutual Recognition and Decentralised Procedures, CMD(v) and subsequently the Committee for Medicinal Products for Veterinary Use (CVMP).

Denmark considered that the proposed testing regime to demonstrate freedom from extraneous agents was insufficient to ensure that Bovilis BVD/Bovilis BVD-MD would not interfere with their national eradication campaigns for certain animal diseases and that, therefore, the benefit/risk assessment for Bovilis BVD/Bovilis BVD-MD was unfavourable, authorisation of the product representing a potential serious risk to animal health.

During its meeting of November 2006, the CVMP started a referral procedure under Article 33(4) of Directive 2001/82/EC as amended for Bovilis BVD/Bovilis BVD-MD. The Marketing Authorisation Holder was requested to provide all supporting data to justify a positive benefit-risk ratio for the treated animal.

The CVMP considered that in general, the absence of extraneous agents in vaccines can be ensured by:
1. GMP compliance of the production system
2. Extraneous agents testing of raw materials
3. Extraneous agents testing of batches of finished product, if required.

The production and testing of Bovilis BVD vaccine are in accordance with the relevant requirements of Directive 2001/82/EC, the relevant EU guidelines and the relevant monographs of the Ph.Eur.

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The CVMP concluded that the production of Bovilis BVD vaccine is in compliance with GMP requirements, that extraneous agent testing of raw materials are carried out according to the relevant requirements and that extraneous agent testing of finished batches of Bovilis BVD for FMDV, BLV, BTV and IBRV is not required in the relevant monographs.

Therefore the requested additional specified extraneous testing requirement was not scientifically justified for Bovilis BVD.

CVMP have noted the inconsistencies (with regard to extraneous agents testing) in the Ph.Eur. monographs for inactivated bovine vaccines and have written to the EDQM and asked them to address this.

The CVMP concluded that the benefit - risk assessment for Bovilis BVD was favourable. The CVMP Opinion was adopted on 17 April 2007 and the subsequent Commission Decision on 29 June 2007.
